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Congress of the United States
House of Representatives
Washington, DC 20515–2107

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The Honorable William H. Donaldson
Chairman
Securities and Exchange Commission
450 Fifth Street, N.W.
Washington, DC 20549

Dear Chairman Donaldson:

I am writing to request information regarding the Commission's views regarding the obligation of publicly-traded pharmaceutical companies to disclose to their investors information relating to their compliance with certain requirements established by the Food and Drug Administration (FDA).

As part of the Food and Drug Modernization Act of 1997 (Public Law 105-115), Congress amended the Federal Food Drug and Cosmetic Act to give the FDA the authority to grant accelerated approval to certain drugs, on the condition that the company producing the drug committed to conducting appropriate post-marketing confirmatory studies. The new law (21 U.S.C. 356) allows the Secretary, at the request of a sponsor of a new drug, to "facilitate the development and expedite the review of such drug if it is intended for the treatment of a serious or life-threatening illness." Under this provision, the drug company does not have to meet the normal FDA standards of establishing its safety and effectiveness. Instead, the drug can be approved based only "upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

In order to ensure that drugs approved under this fast track process were actually safe and effective, however, the law also provides that:

> "*The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if--*
>
> *(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;*
>
> *(B) a post-approval study of the fast track product fails to verify clinical benefit of the product;*
>
> *(C) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or*
>
> *(D) the sponsor disseminates false or misleading promotional materials with respect to the product."*

A drug company's failure to conduct a required post-approval study, the failure of such a study to verify clinical benefits, or evidence uncovered in such a study that the fast track drug was not safe or effective could lead to the expedited withdrawal of the product from the market by the FDA. Obviously, any of these outcomes could result in significant financial losses to the drug company that was selling the fast-track drug. It would therefore appear to me that full and complete disclosure regarding the status and outcome of any federally-mandated post-approval studies would be material information which should be included in the companies' SEC filings.

On March 15, 2004, the FDA submitted a report to Congress regarding the progress of required post-marketing studies. According to that report, as of September 30, 2003, only 33% of required drug studies and 62% of required biologics studies were reported by the FDA as proceeding on schedule or as having been completed.

The FDA's Center for Drug Evaluation and Research also maintains a database of all post-marketing commitments. This database is available at:
http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm

I am concerned that companies may not be fully reporting information regarding their obligation to carry out post-marketing studies, the status of such studies, or the implications of a failure to complete the study or of any adverse findings which might arise as a result of such studies. As a result, I am concerned that investors may be mislead into believing that a company may be giving an impression to investors that drugs they produce have been fully approved by the FDA as safe and effective, when in fact the drug has been given only a conditional approval which is subject to revocation.

I would like some more information regarding the SEC's views of this matter. In this regard, I request your assistance in providing answers to the following questions:

1. Do you agree that the status of post-marketing study commitments is material in light of the fact that failure to meet this commitment, or adverse results discovered as a result of such a study, could lead to an expedited withdrawal of the approved product?
2. Do you agree that a company whose post-marketing study is delayed is obligated to report this status to their investors in light of the fact that delayed status could potentially lead to an expedited FDA withdrawal of the approved product?
3. Do companies that have entered into such post-marketing agreements routinely report the status of these required studies to their investors?
4. Based on a review of the FDA's reporting on post-marketing studies of fast track drugs, the FDA's database of post-marketing commitments, and its review of disclosure documents filed with the SEC, is the Commission satisfied that all publicly-traded drug companies are fully disclosing all material information about the status and results of such studies, and that there are no material omissions in such disclosures?
5. If not, please explain what action, if any, the Commission is taking in response.
6. Has the Commission staff ever returned or rejected a proposed filing based (in whole or in part) on a failure to disclose such information?
7. Has the SEC ever taken any enforcement or other regulatory action with regard to any companies that may have failed to provide this information to their investors?

Thank you for your assistance and cooperation in this matter. Should you have any questions about this request, please contact Ms. Katharine Reinhalter or Mr. Jeffrey Duncan of my staff at 202-225-2836.

Sincerely,

Edward J. Markey

Edward J. Markey
Member of Congress